ORIGINAL ARTICLE

Emerging Trends in Cancer Care: Health Plans' and Pharmacy Benefit Managers' Perspectives on Changing Care Models

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Background: Cancer care in the United States is being transformed by a number of medical and economic trends, including rising drug costs, increasing availability of targeted therapies and oral oncolytic agents, healthcare reform legislation, changing reimbursement practices, a growing emphasis on comparative effectiveness research (CER), the emerging role of accountable care organizations (ACOs), and the increased role of personalization of cancer care.

Objective: To examine the attitudes of health plan payers and pharmacy benefit managers (PBMs) toward recent changes in cancer care, current cost-management strategies, and anticipated changes in oncology practice during the next 5 years.

Methods: An online survey with approximately 200 questions was conducted by Reimbursement Intelligence in 2011. The survey was completed by 24 medical directors and 31 pharmacy directors from US national and regional health plans and 8 PBMs. All respondents are part of a proprietary panel of managed care decision makers and are members of the Pharmacy and Therapeutics Committees of their respective plans, which together manage more than 150 million lives. Survey respondents received an honorarium for completing the survey. The survey included quantitative and qualitative questions about recent developments in oncology management, such as the impact on their plans or PBMs of healthcare reform, quality improvement initiatives, changes in reimbursement and financial incentives, use of targeted and oral oncolytics, and personalized medicine. Respondents were treated as 1 group, because there were no evident differences in responses between medical and pharmacy directors or PBMs.

Results: Overall, survey respondents expressed interest in monitoring and controlling the costs of cancer therapy, and they anticipated increased use of specialty pharmacy for oncology drugs. When clinical outcomes are similar for oral oncolytics and injectable treatments, 93% prefer the oral agents, which are covered under the specialty tier by 59% of the plans. The use of the National Comprehensive Cancer Network practice guidelines for coverage and reimbursement of oncologic agents is reported as "very frequent" by 10% of survey respondents, "frequent" by 21%, and "moderately frequent" by 7%. Most (66%) respondents believe that it is probable and 3% believe it is highly probable that healthcare reform will help to control oncology treatment costs, although 59% also predict an increase in utilization restrictions and 48% predict more stringent comparative effectiveness evidence requirements. The survey reveals a considerable uncertainty among health plans and PBMs about the eventual impact of ACOs on oncology care. Although 82% of those surveyed believe that measures such as increasing adherence to evidence-based treatments will achieve cost-savings, nearly half (48%) had no plans to use such measures.

Conclusions: Recent trends in healthcare legislation, rising drug costs, and changing reimbursement practices are poised to significantly alter conventional models of cancer care delivery and payment. The results of this survey indicate that health plans and PBMs anticipate greater use of evidence-based management strategies, including CER, quality initiatives, and biomarker testing for appropriate cancer therapy selection. In addition, they anticipate greater focus on cost control, with a greater role for utilization management and increased patient cost-sharing. Finally, there is a high level of uncertainty among plans and PBMs about the eventual impact of ACOs and other aspects of healthcare reform on oncology practice.

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According to the American Cancer Society, more than 1.6 million new cancer cases will be diagnosed in 2012, and more than 577,000 Americans are expected to die of cancer this year.[1] Currently, claims for cancer care account for 10% of total healthcare costs but for less than 1% of a typical commercially insured population.[2] Cancer drugs are the third most expensive category among specialty drugs, with an average cost per prescription of $3259.[3] It has been estimated that with the aging of the US population, the annual number of newly diagnosed cases of cancer will increase by approximately 45%, to 2.3 million, by 2030.[4] As a result of advances in cancer diagnosis and treatment over the past several decades, the 5-year survival rate for all cancers increased from 49% for patients diagnosed between 1975 and 1977, to 67% for those diagnosed between 2001 and 2007.[1]

Several important trends are currently changing the oncology management marketplace. Oral oncolytics, once uncommon, now account for approximately 25% of all drugs in the oncology pipeline.[5] Healthcare reform legislation has been introduced with the goal of improving patient outcomes while reducing overall cost, and this legislation is likely to significantly alter traditional models of care delivery, assessment, and reimbursement. Advances in cellular and molecular biology have made it possible to target a patient's unique tumor biology, but the new targeted agents are considerably more expensive than older cancer medications. For example, an analysis of monthly Medicare costs for a typical patient (70 kg body weight or 1.7 m^2 body surface area) showed that costs exceeded $5000 per month for several targeted agents, including sorafenib ($5097), nilotinib ($6140), panitumumab ($7991), cetuximab ($9465), and alemtuzumab ($19,925).[6] In contrast, the costs for most cytotoxic drugs introduced before 1995 were less than $1000 monthly.[6]

Compared with older treatments, many newer chemotherapy agents are much more expensive; this includes bendamustine ($7023 monthly), ixabepilone ($6781 monthly), and nelarabine ($19,425 monthly).[6] In addition, many of these agents require histologic, genetic, or molecular tests to identify appropriate patients for a specific cancer therapy, for example, HercepTest (Dako) or Ventana Pathway (Ventana), used to predict response to trastuzumab in patients with breast cancer.[7] Test costs may vary from approximately $350 to ≥$4000 per test.[8]

The economic impact of targeted therapies may be expected to grow as clinical trials continue to explore new applications of these agents, including their use as first-line therapy and/or in combination with other high-cost targeted agents (eg, the combination of erlotinib and bevacizumab in patients with lung cancer, or lenalidomide plus bortezomib in patients with multiple myeloma). Newer diagnostic approaches, such as increasing use of positron emission tomography, also contribute to increasing costs of cancer care.[9]

KEY POINTS

- Cancer care is undergoing changes related to new clinical and economic trends, including rising drug costs of biologic therapies, changing reimbursement practices, a growing emphasis on comparative effectiveness research, and potential changes related to healthcare reform.
- This survey of 55 health plans and PBMs explored their perspectives on these emerging changes and their anticipated cost-management strategies in oncology.
- The survey findings indicate an increasing role for specialty pharmacy for cancer drugs, a growing focus on cost-control efforts, and a significant impact of national practice guidelines on formulary and reimbursement decisions for cancer therapies.
- National guidelines serve as compendia for reimbursement purposes for approved and off-label uses of cancer therapies.
- Quality initiatives are perceived as having the greatest potential impact on breast cancer.
- Seventy-nine percent of health plans and PBMs participating in this survey do not have a specific price threshold for placing drugs on the specialty tier.
- The decision to cover a particular cancer test is significantly influenced by clinical practice guidelines, according to 90% of survey respondents.
- These findings highlight important trends in oncology management and reimbursement that reinforce the continuing efforts by payers to control costs while maintaining quality of care.

The rising healthcare costs associated with more recent cancer diagnostics and treatments are a significant concern for many health plans. To understand current oncology cost-management strategies, as well as expectations about future practice patterns of healthcare payers and pharmacy benefit managers (PBMs) in response to changes in oncology care, Reimbursement Intelligence conducted an online survey of health plans and PBMs to determine their attitudes and expectations about cancer management.

Survey Methodology

Reimbursement Intelligence, a market research company, conducted an online survey of approximately 200 questions in October 2011. The survey was completed by 55 (of 57) medical and pharmacy directors (24 medical

Table 1 Current and Anticipated Oncology Management Tactics

Management tactics	Not utilized, %	Currently utilized, %	Likely to be utilized in the next 2 years, %
NCCN/ASCO guidelines	10	76	14
Pharmacy benefit classification	21	65	14
ASP-based payments	21	58	21
Biomarker testing for appropriate therapy selection	10	52	38
Quality initiatives	28	41	31
Episode of care payments	55	17	28
Oncology formulary with preferred brand	45	17	38

ASCO indicates American Society of Clinical Oncology; ASP, average sales price; NCCN, National Comprehensive Cancer Network.

directors and 31 pharmacy directors) from US national and regional health plans and 8 PBMs. Survey respondents were formulary decision makers for oncology coverage at health plans and PBMs, who together manage more than 151 million covered lives, including individuals enrolled in commercial, Medicare Advantage, and Managed Medicaid plans. The most frequent benefit design in these companies is a 3-tier open formulary, which was used by 48% of health plans and PBMs; a 3-tier closed design was used by 21%; a 4-tier design with a specialty pharmacy plan by 17%; a 2-tier design by 7%; and other benefit designs by 7%.

All survey respondents are also part of a proprietary panel of managed care decision makers and are members of the Pharmacy and Therapeutics Committees of their respective plans. Respondents received an honorarium for completing the survey. The survey included quantitative and qualitative questions about several aspects of oncology management, including the application of clinical practice guidelines in cancer care, the potential impact of healthcare reform, quality improvement initiatives, and personalized medicine. The respondents were treated as 1 group, because no differences in responses were evident between medical and pharmacy directors or PBMs.

Results

Cost-Management Strategies for Oncology

Drugs prescribed by oncologists currently account for more than 40% of all Medicare drug spending.[10] According to the National Institutes of Health, the direct costs of cancer care in the United States are expected to increase from approximately $124 billion annually in 2010 to approximately $173 billion in 2020 (a 39% increase).[11] Most cancer drugs approved since 2005 cost more than $4000 monthly, and a full course of treatment with some targeted therapies costs more than $80,000.[6,12]

The rising cost of cancer care comes at a time when legislative changes to Medicare reimbursement policies have markedly decreased the reimbursement that physicians receive for prescribing many oncology drugs, in some cases leaving prescribers in debt for oncology drugs that they must purchase.[13]

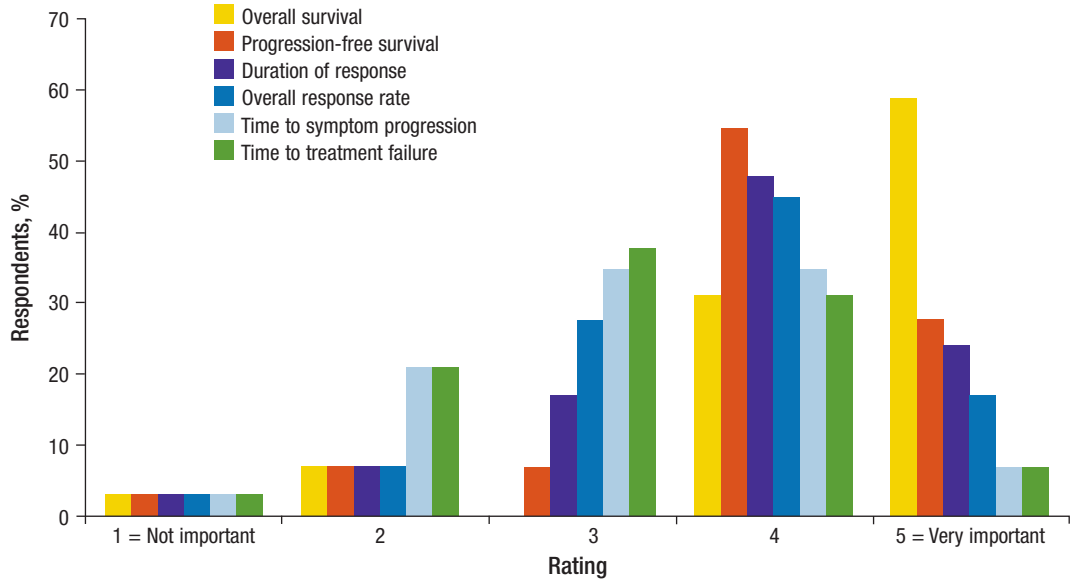
Qualitative surveys and interviews of senior physician executives at large managed care organizations (MCOs), which were conducted by the National Comprehensive Cancer Network (NCCN), identified several strategies that these MCOs were using to control costs and maximize clinical benefit.[9] These cost-control strategies include aggressive contracting, new reimbursement models (eg, payments based on episodes of care rather than on oncologic drug costs), nursing-led case-management strategies focused on patients with the greatest medical needs, the use of NCCN guidelines and other resources to establish standards of treatment and reimbursement, and the use of specialty pharmacy services for high-cost oral drugs.

Cost-management strategies in current use by respondents to the present survey, as well as strategies expected to be initiated within the next 2 years, are summarized in **Table 1**. Participants were asked to rate each cost-management tactic as either currently utilized, not currently utilized but likely to be utilized within the next 2 years, or not utilized and with no plans for utilization within the next 2 years. The use of clinical practice guidelines from the NCCN or the American Society of Clinical Oncology (ASCO), as well as moving a drug from the medical benefit to the pharmacy, are the most frequently utilized management tactics (by 76% and 65%, respectively), whereas biomarker testing and the use of preferred brands on the oncology formulary are the strategies most likely to be introduced in the next 2 years.

Survey respondents report that oncologist responses to declining reimbursement rates include consolidation of oncology clinics (35%), selecting more profitable therapy options (35%), sending more patients for hospitalization (31%), forming joint ventures or partnerships with hospital groups (21%), and increasing practice efficiency (17%).

Figure 1 Overall Survival and Progression-Free Survival the Most Important Efficacy End Points When Evaluating Coverage of Cancer Therapies

Question: Please rate each of the following efficacy end points in terms of their importance and influence when evaluating cancer therapies for coverage and reimbursement.



In this survey, breast cancer was rated as the most expensive cancer type overall, followed by non–small-cell lung cancer, prostate cancer, multiple myeloma, non-Hodgkin lymphoma (NHL), and metastatic melanoma. Techniques used to monitor oncology drug costs include per-member per-month costs (by 69% of respondents); utilization review (41%); and analysis by cancer diagnosis (31%), episode of care (21%), disease type (21%), or tumor type (17%). Only 10% of respondents say that their organization does not monitor oncology costs.

A recent trend in oncology care has been the growing number of health plans that use a 4-tier pharmacy benefit structure, with specialty pharmacy coinsurance payments of 10% to 25% of the drug costs.[14] In this survey, copayments at tier 4 are reported as $21 to $40 by 5% of plans/PBMs and >$40 by 26%, whereas 68% of plans/PBMs use coinsurance. Within the next 5 years, most respondents expect that between 11% and 40% of cancer therapies would go through specialty pharmacy. Most (79%) plans/PBMs in this survey do not have a specific price threshold for placing drugs on the specialty tier.

When clinical end points are similar, 93% of respondents prefer oral agents to infused therapies, 7% are neutral, and none finds infused agents to be superior. Of note, although oral oncolytics offer greater patient convenience, they are also associated with increased likelihood of nonadherence, resulting in adverse outcomes and greater resource utilization.[15] In fact, reported adherence rates have varied widely, from 16% to 100%.[15] In companies included in this survey, oral oncolytic agents are covered under the specialty drug tier by 59% of plans/PBMs. In terms of the preferred type of tracking data to assess patient adherence, 58% of respondents prefer the medication possession ratio, and 42% prefer claim or refill information.

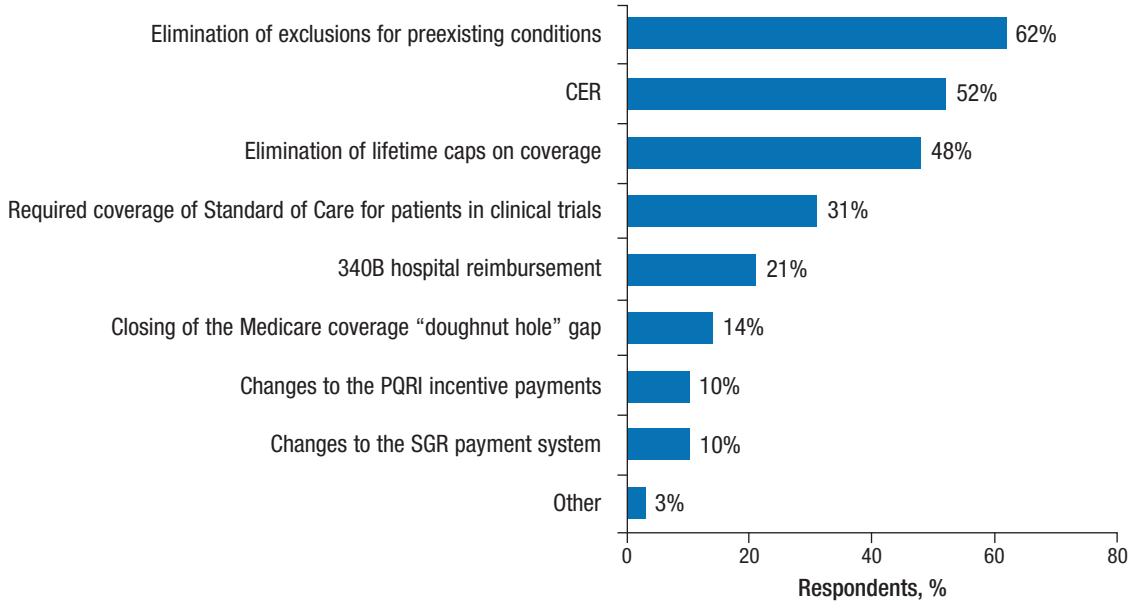
A key distinction between oral and injectable cancer medication coverage is that oral agents are covered by Medicare under the pharmacy benefit, which may mean higher coinsurance or cost burden for patients, including the potential of falling into the Medicare coverage "doughnut hole." In contrast, office-infused agents are generally covered by the medical benefit, with fewer out-of-pocket costs for patients. Although Medicare beneficiaries must pay a 20% copayment for drugs administered under the medical benefit, approximately 90% have supplemental insurance under Medicare part B, which covers this amount.[16] Physicians may take these factors into account when making therapy decisions.

Role of Practice Guidelines in Treatment Selection and Reimbursement Considerations

Clinical practice guidelines from the NCCN and ASCO use data from large, well-designed clinical trials, combined with supporting evidence from retrospective

Figure 2 Elimination of Exclusion for Preexisting Conditions and CER Are Expected to Have the Greatest Impact on Oncology Management

Question: What aspects of the healthcare reform legislation will have the most impact on your approach to management of oncology therapies? Please choose all that apply.



CER indicates comparative effectiveness research; PQRI, Physician Quality Reporting Initiative; SGR, Sustainable Growth Rate.

studies and other data sources, to identify treatment regimens that produce the best possible clinical outcomes for patients with different types of cancer. The guidelines use disease stage and other patient factors to identify preferred and alternate regimens, which are continually revised and updated as new data become available. These guidelines serve as standards of medical care and as compendia for reimbursement for approved and for off-label uses of antitumor agents.[17] For example, the continued use of bevacizumab for the treatment of breast cancer has been recommended by the NCCN guidelines, even after the withdrawal of the US Food and Drug Administration indication for this purpose.[18]

Participants were asked how frequently self-insured employers or employee benefit consultants require the use of NCCN guidelines when soliciting bids for oncology pharmacy management services. The use of clinical practice guidelines for coverage or reimbursement is "very frequent" (occurring in >75% of all requests for proposals [RFPs]) by 10% of respondents, "frequent" (51%-75% of all RFPs) by 21% of respondents, "moderately frequent" (26%-50% of all RFPs) by 7%, and "used in some instances" (10%-25% of all RFPs) by 14% of respondents. Only 14% say that clinical guidelines are not used at all, and the remaining 34% consider the question not applicable to their contracting practices. Data sources required for off-label reimbursement include NCCN guidelines (72%), compendia listings (66%), and peer-reviewed articles in the medical literature (66%). Other requirements for off-label treatment include failure of on-label therapy (52%), prior authorization (52%), and prescribing physician documentation (28%).

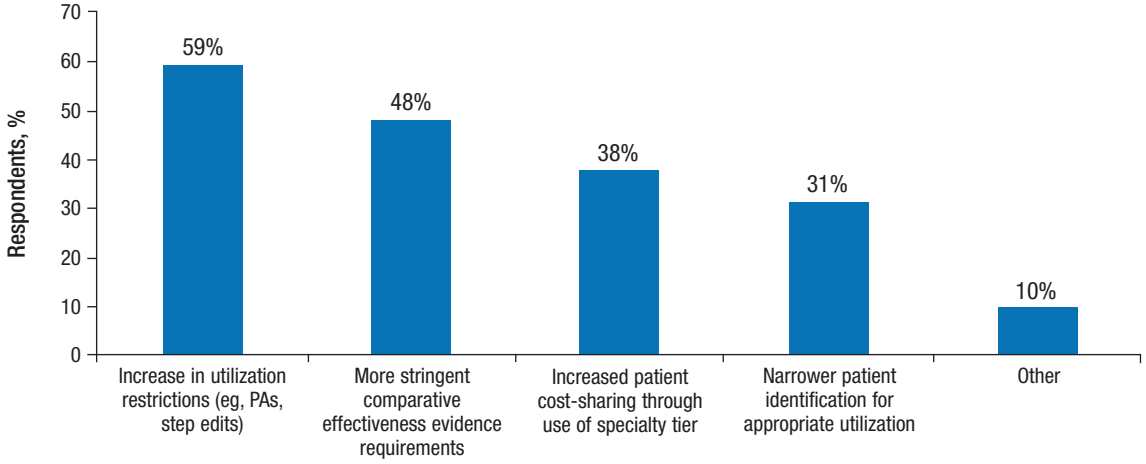
Participants were also asked to rate the importance, on a scale of 1 (not important) to 5 (very important), of different efficacy end points that they consider when evaluating cancer therapies for reimbursement. Overall survival (OS) is the most important efficacy end point, with a rating of "very important" by 59%; progression-free survival (PFS) was rated as "very important" by 28%; and duration of response by 24% (**Figure 1**).

Healthcare Reform and Comparative Effectiveness Research

The Patient Protection and Affordable Care Act (ACA) was signed into law on March 23, 2010. The goals of the ACA include expanding access to health insurance coverage, improving affordability and sustainability for those with coverage, controlling healthcare

Figure 3 Healthcare Reform Expected to Lead to Greater Utilization Restrictions and More Stringent CER Requirements

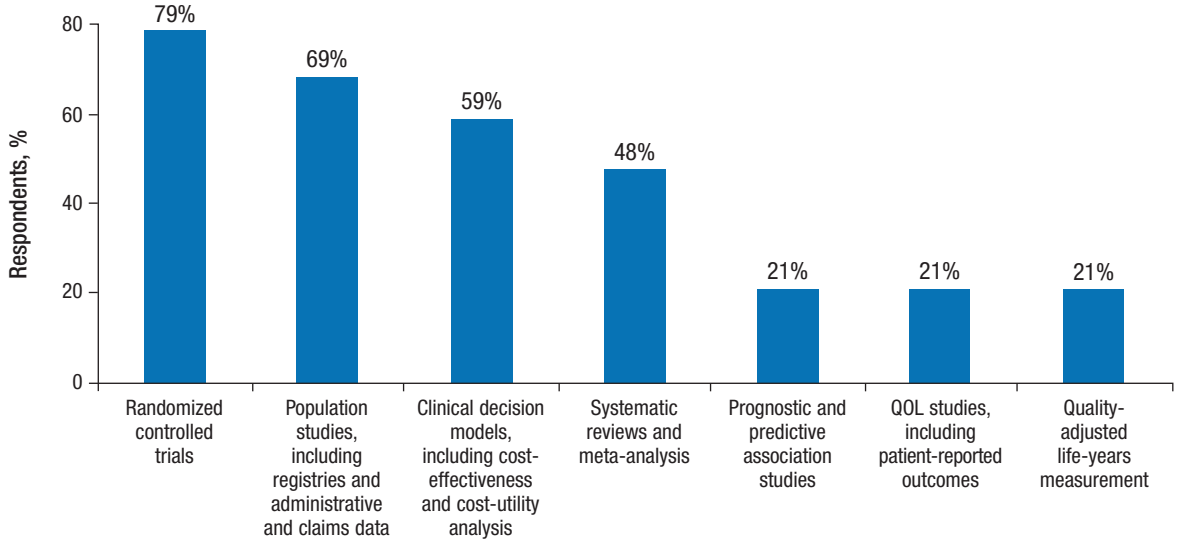
Question: How will the healthcare reform legislation impact your management of oncology agents? Please check all that apply.



CER indicates comparative effectiveness research; PAs, prior authorizations.

Figure 4 Randomized Controlled Trials and Population Studies Expected to Have the Most Impact on Cost of Care and Drug Utilization

Question: Which CER methodologies will have the greatest impact on cost-efficient care and drug utilization? Please check all that apply.



CER indicates comparative effectiveness research; QOL, quality-of-life.

Table 2 Primary Drivers for Forming/Partnering with an ACO

Item	Overall rank
Improve quality of care and performance standards	1
Increase lower-cost treatment alternative utilization	2
Improve outcomes data tracking	3
Improve overall spending tracking	4
Improve patient drug compliance	5
Improve physician adherence to the formulary	6
Implement pay-for-performance	6
Legislative requirement for Medicare beneficiaries	7

ACO indicates accountable care organization.

costs, and improving the quality of care.[19] The ACA is expected to standardize coverage by defining a number of significant changes in oncology practice, including elimination of exclusions for preexisting conditions or lifetime caps on coverage, coverage of routine care for patients participating in clinical trials, changes in reimbursement, and expanded access to the federal 340B drug discount pricing program.[19-22] In addition, the US American Reinvestment and Recovery Act of 2009 promotes comparative effectiveness research (CER) through a separate $1.1 billion appropriation to fund clinical studies that will compare efficacy, safety, and other primarily clinical outcomes associated with 2 or more treatments for the same medical problem.[23]

CER methodologies that are expected to have the greatest impact on cost of care and drug utilization include randomized controlled clinical trials, population studies, and clinical decision models.

When asked to identify aspects of healthcare reform legislation that will have the greatest impact on oncology management, elimination of exclusions for preexisting conditions was selected by 62% of respondents, followed by the use of CER (52%), eliminating lifetime caps on coverage (48%), required coverage for patients in clinical trials (31%), and increased number of hospitals eligible for the federal 340B drug discount (21%; **Figure 2**).

Regarding the impact of healthcare reform on the management of cancer drugs, most respondents (59%) expect that healthcare reform measures would lead to greater utilization restrictions, such as prior authorizations or step edits; 48% anticipate the use of more stringent requirements for comparative effectiveness evidence; 38% anticipate greater patient cost-sharing through the use of a specialty pharmacy tier; and 31% expect narrower patient identification for appropriate utilization (**Figure 3**).

CER methodologies that are expected to have the greatest impact on cost of care and drug utilization include randomized controlled clinical trials, population studies, and clinical decision models (**Figure 4**). In addition, most respondents (66%) believe that it is probable, and 3% believe that it is highly probable, that CER will help control oncology costs and healthcare utilization; 10% consider this outcome to be highly improbable or improbable; and 21% are neutral on this question. CER is expected to help identify the most effective interventions to improve care by 76% of payers. None of the plans surveyed are currently involved in new CER models.

Accountable Care Organizations

Accountable care organizations (ACOs) are affiliations of healthcare providers that are held jointly accountable for improving care quality and reducing spending.[24] ACOs are established by the ACA as a new payment model under Medicare, Medicaid, and private insurance.[25] They are intended to reduce fragmentation of care,[26] although their precise implementation in oncology practice remains uncertain. Primary care physicians may join only 1 ACO; oncologists may join 2 or more ACOs as independent physicians, but they are not permitted to launch new ACOs.

When asked to rate their overall impressions of ACOs, 48% of surveyed respondents were neutral, 38% were favorable or highly favorable, and 14% were unfavorable or highly unfavorable. Those with negative opinions of ACOs emphasize factors such as the resemblance of ACOs to the "gatekeeper" role of HMOs, potential barriers to care for rural patients, and the difficulties involved in moving physicians from private practice to employee status. Those with positive opinions of ACOs note the potential for improved care management and the use of incentives to align primary care physicians, specialists, and hospitals.

Participants view ACOs as moderately relevant (52%), relevant (31%), or very relevant (7%) to oncology care; only 10% say that ACOs are not relevant to oncology. In addition, 24% believe that they would form or partner with an ACO within the next 2 years, and another 41% say that such a move is possible. Of those

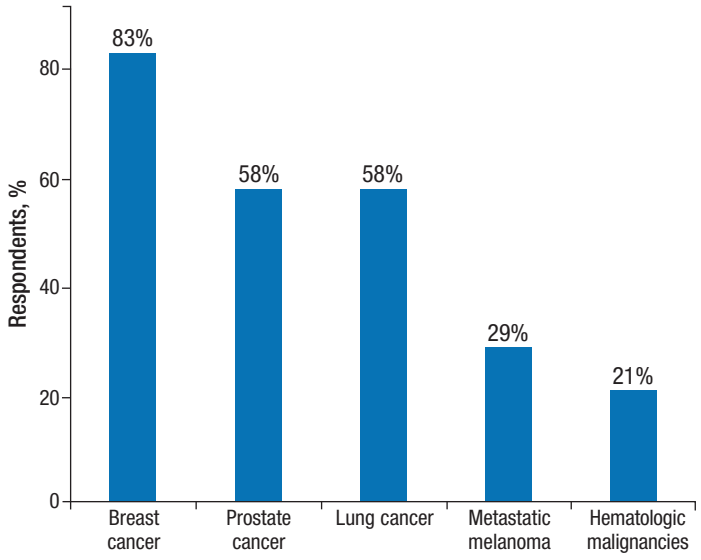
indicating having plans to form or partner with an ACO, 16% plan to address the Medicare population, 26% the commercial population, and 58% both populations. The primary drivers for forming or partnering with an ACO are shown in **Table 2**.

Although the US Department of Health and Human Services operates an ACO pilot program (the Pioneer Accountable Care Organization Model program),[27] only 31% of respondents expressed an interest in participating in that program. Lack of interest in a pilot program, a perception of the program as overly cumbersome, or competition with other priorities were cited as reasons for nonparticipation in the Pioneer ACO pilot program.

Most (76%) respondents believe that ACOs would result in cost-savings of 1% to 30%; 18% believe that ACOs would yield no cost-savings, and 4% believe that cost-savings would likely exceed 40%. They expect that the cost-savings would be generated primarily through greater adherence to evidence-based treatments, improvement in coordination of care, and greater use of low-cost alternative treatment options. ACOs are considered most likely (83% of respondents) to yield cost-savings in the treatment of breast cancer (**Figure 5**). Other cancer types expected to yield cost-savings include prostate cancer (identified by 58%), lung cancer (58%), metastatic melanoma (29%), and hematologic malignancies (21%).

Figure 5 ACOs Expected to Generate the Greatest Cost-Savings in the Treatment of Patients with Breast Cancer

Question: *In which types of cancer indications do you expect to see the biggest cost-savings to your plan as a result of your formation/partnership with an ACO? Please check all that apply.*



ACO indicates accountable care organization.

Quality Initiatives

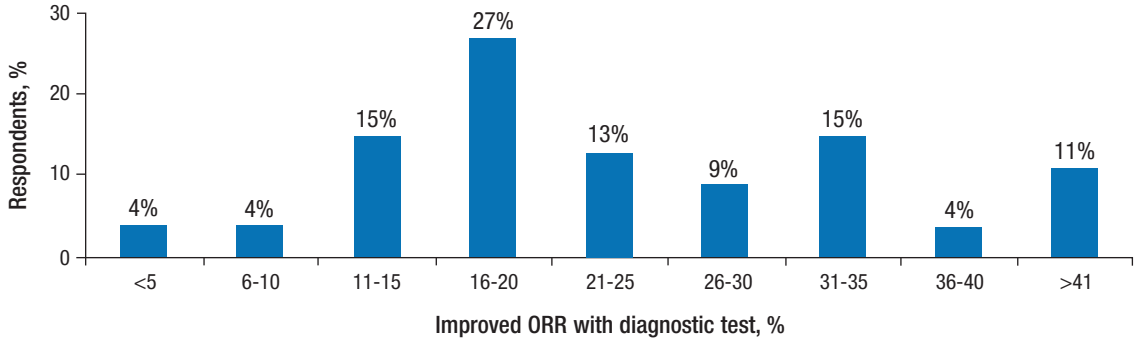
Over the past decade, several initiatives have been developed to quantify and improve the quality of care received by patients with cancer. ASCO has sponsored the development and dissemination of the Quality Oncology Practice Initiative (QOPI), a voluntary, physician-led program that is designed to improve oncology practice by identifying general performance measures, as well as specific performance measures for breast, colon, lung, and rectal cancer, and NHL.[28] The NCCN and ASCO have also developed a simplified set of quality measures for breast and colorectal cancer.[29] The Physician Quality Reporting System (PQRS), formerly known as the Physician Quality Reporting Initiative (PQRI), was established by the Centers for Medicare & Medicaid Services as a voluntary reporting system that is linked to financial incentives for eligible healthcare professionals who provide care to Medicare recipients.[30]

Health plans are experimenting with a variety of approaches to manage costs associated with oncology care, while also ensuring that patients receive care that meets evidence-based standards. For example, United Healthcare has been evaluating the effects of a "bundled" payment pilot program in 5 oncology practices, in which these practices receive an up-front fee for the full cost of care for each episode of cancer care rather than purchasing cancer medications and receiving reimbursement for these purchases. This approach is intended to standardize cancer care and encourage greater adherence to treatment guidelines, while separating evidence-based medication prescribing from drug reimbursement.[31] A quality improvement program led by the University of Michigan, in coordination with Blue Cross Blue Shield, has been developed to increase the statewide use of breast cancer treatments that meet benchmarks recommended by the NCCN, including appropriate use of endocrine therapy, chemotherapy, and radiation therapy.[32]

In this present survey, nearly half (48%) of respondents have no plans to implement quality initiatives, 35% plan to implement quality measures created by the NCCN, 24% plan to implement the ASCO QOPI, 7% plan to implement the PQRS/PQRI measures, and 3% plan to implement other quality measures. Quality initiatives are believed to have the greatest potential impact on breast cancer, with 83% agreeing that initiatives would improve the care of patients with breast cancer, followed by prostate cancer (48%), lung cancer (45%), hematologic malignancies (21%), and metastatic melanoma (17%). In addition, 35% say that quality ini-

Figure 6 A Companion Diagnostic Test Must Improve ORR by 11% to 30% in the Targeted Population Compared with Untested Patients for Reimbursement Consideration

Question: For your organization to reimburse a diagnostic test relevant to a targeted treatment, what level of clinical benefit (such as ORR) does a diagnostic test need to show versus all-comers?



ORR indicates overall response rate.

tiatives are unlikely to significantly affect any indication.

Survey respondents believe that quality initiatives have the potential to improve the use of evidence-based treatments (97%), including a reduction in the use of imaging studies without compelling clinical evidence (52%) and an increase in patient–provider discussions about palliative care (35%). However, the respondents were split on the types of incentives they would offer for participation in quality initiatives: 31% would offer a percentage of cost-savings, 7% would offer incentives based on quality achievements, 28% would not offer incentives, and 35% were unsure about the types of incentives they would offer.

Personalized Medicine: The Role of Diagnostics and Tumor Markers

Targeted therapies make it possible to modulate cellular signal transduction pathways that are important in tumor growth and development, whereas new genetic and molecular tests make it possible to identify individual patients who are most likely to benefit from a particular treatment strategy and to predict toxicity reactions.[33-35] Greater individualization of therapy may also help to reduce overall costs by identifying patients who are not appropriate candidates for certain treatments. Examples of biomarkers that are used in treatment selection include biomarkers for the expression of epidermal growth factor receptor mutations to predict response to erlotinib in patients with advanced lung cancer,[36] as well as biomarkers for overexpression of the HER2 protein to predict trastuzumab response in patients with breast cancer.[37]

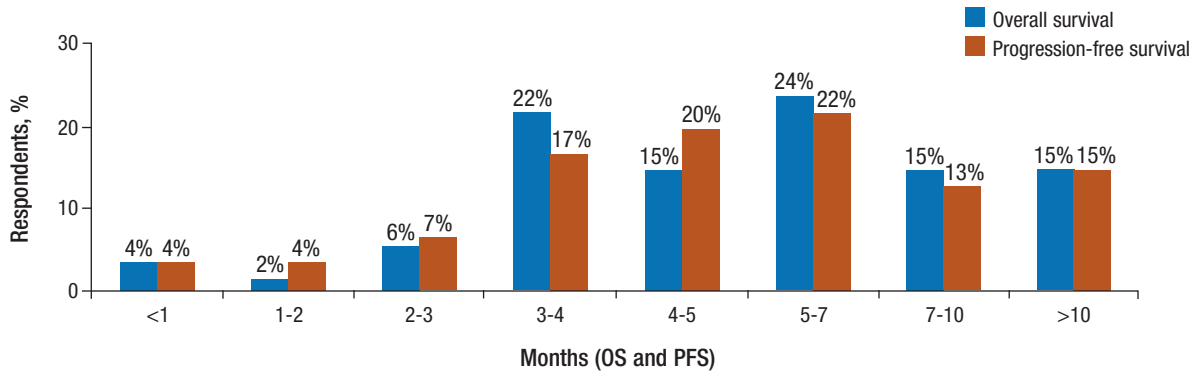
The decision to cover a particular oncology diagnostic test is significantly influenced by published clinical practice guidelines, according to 90% of survey respondents. ASCO and NCCN guidelines are the most influential in determining genetic test coverage, and both are cited as important by 73% of those surveyed. Regarding the types of information that would be needed to increase the acceptance of genetic testing, proof of greater specificity/sensitivity was identified by 79% of respondents, cost-effectiveness data by 62%, identification of more clinically meaningful targets by 48%, and clinical trials with larger sample sizes by 35%. For reimbursement, a majority (64%) of respondents agree that a companion diagnostic test must produce an improvement in the overall treatment response rate between 11% and 30% in the target population compared with untested patients (**Figure 6**). In addition, a companion diagnostic test must improve OS or PFS by 3 to 7 months in the targeted population for the test to be reimbursed (**Figure 7**).

Discussion

Few recent studies have surveyed managed care professionals regarding their views on oncology cost-management strategies and expectations for future trends. One recent study conducted by the NCCN was based on interviews with physician executives at MCOs to identify their perspectives on the oncology marketplace, and the measures they used to address the cost and quality of cancer care.[9] Frequently used cost-control strategies included aggressive contracting, new reimbursement models, case management, use of NCCN guidelines to establish treatment standards, and the use of specialty pharmacy services.[9]

Figure 7 A Companion Diagnostic Test Must Improve OS or PFS by 3 to 7 Months in the Targeted Population over All-Comers for Reimbursement Considerations

Question: *For your organization to reimburse a diagnostic for a targeted treatment, what level of clinical benefit (such as PFS or OS) does a diagnostic test need to show versus all-comers?*



OS indicates overall survival; PFS, progression-free survival.

Our survey has evaluated viewpoints of managed care professionals in the present, at a time when oncology management costs are rising rapidly, and there is yet considerable uncertainty about the eventual impact of healthcare reform on oncology practice. Key insights from this present survey include:

- Health plans and PBMs expect to see increased use of specialty pharmacy services during the next 5 years
- When clinical outcomes are similar, respondents overwhelmingly prefer oral oncolytic agents to injectable chemotherapy drugs
- Clinical guidelines are frequently used to establish coverage and reimbursement criteria, including those for off-label uses; when evaluating different treatments, OS is considered the single most important clinical end point
- Most respondents believe that healthcare reform efforts would help to control oncology costs, but that these measures would also result in greater utilization restrictions
- Nearly all respondents view ACOs as relevant to oncology care; however, many have not yet formed an opinion about whether the impact of ACOs would likely be positive or negative, and interest in participating in pilot programs is generally low
- Quality improvement measures are perceived to have the potential to improve cancer care and the use of evidence-based treatments, yet nearly half of the respondents have no plans to use such measures
- Participants believe that ACOs and quality improvement measures have the greatest potential impact on the treatment of breast cancer
- ASCO and NCCN guidelines are important considerations in reimbursement decisions for genetic testing.

Conclusion

The survey findings highlight important emerging trends in oncology management, as well as informing the coordination of cost and clinical management of patients with cancer. In general, health plans and PBMs show a great deal of interest in monitoring and controlling costs of cancer therapy. Published guidelines from ASCO and the NCCN are central to payer views about treatment selection, reimbursement, off-label prescribing, and genetic testing. CER is believed to help identify better treatment options and control costs, although most respondents also believe that healthcare reform would lead to more restrictions on the use of some cancer therapies. ACOs generated the greatest uncertainty among the topics included in this survey; although respondents expect ACOs to significantly affect oncology management over the next 2 years, most are not yet planning to form or join such an organization, and their attitudes in general toward ACOs remain largely neutral. In addition, there is a significant gap between payers' perceptions about the potential benefit of quality improvement measures and their plans to use such measures at their own organizations. When considering the role of genetic testing, respondents expect to see measurable improvements attributable to testing on clearly defined clinical end points, such as overall response rate and duration of OS. ■

Continued

Author Disclosure Statement

Ms Greenapple reported no conflicts of interest.

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STAKEHOLDER PERSPECTIVE

The Cost of Cancer Care: In Search of New Solutions

PATIENTS: The treatment of cancer and the associated cost of cancer care is a topic of major importance for patients and for health plans alike. According to the American Cancer Society, more than 1.6 million Americans will be diagnosed with some form of cancer in 2012 (**Table**).[1]

As a result of advances in cancer diagnosis and treatment during the past several decades, the 5-year survival rate for all cancer types increased from 49% for patients diagnosed between 1975 and 1977, to 67% for those diagnosed between 2001 and 2007.[1] Although more than 577,000 Americans are expected to die of cancer this year, the increased number of patients diagnosed with cancer and the improved long-term survival rates mean that the number of Americans living with cancer will increase by nearly 1 million in 2012.

In addition, it has been estimated that with the aging of the US population, the annual number of newly diagnosed cancers will increase by approximately 45%, to 2.3 million, by 2030.[2]

A recent analysis indicates that the overall US cost of cancer care is approximately 10% of the total healthcare costs.[3] According to a recent Express Scripts report, cancer drugs are the third most expensive category among specialty drugs, with an average cost of $3259 per prescription.[4] Many of these drugs are biologics that have been available for some time;

STAKEHOLDER PERSPECTIVE *(Continued)*

for example, rituximab (Rituxan) was launched in 1997 and trastuzumab (Herceptin) in 1998. These 2 drugs accounted for more than $4.5 billion in US sales in 2011.[5]

In addition, the cancer drug pipeline is robust. A report by the Pharmaceutical Research and Manufacturers of America reveals that US drug manufacturers are testing 981 targeted medicines for cancer, including lung cancer (121 drugs), lymphoma (117 drugs), and breast cancer (111 drugs).[6] The cost of using cancer drugs in the United States is expected to grow by 20% annually, to $173 million by 2020.[7] The annual cost of treatment per patient could top $100,000 for those receiving combination cancer drugs.[7]

Table Estimated Cancer Cases[a] in the United States, 2012

Cancer type in men (N = 848,170)	Estimated cases, %	Cancer type in women (N = 790,740)	Estimated cases, %
Prostate	29	Breast	29
Lung and bronchus	14	Lung and bronchus	14
Colon and rectum	9	Colon and rectum	9
Urinary bladder	7	Uterine corpus	6
Melanoma of skin	5	Thyroid	5
Kidney and renal pelvis	5	Melanoma of skin	4
Non-Hodgkin lymphoma	4	Non-Hodgkin lymphoma	4
Oral cavity	3	Kidney and renal pelvis	3
Leukemia	3	Ovary	3
Pancreas	3	Pancreas	3
All other sites	18	All other sites	20

[a]Excludes basal and squamous skin cell cancers and in situ carcinomas, except urinary bladder.
Source: American Cancer Society. Cancer Facts & Figures 2012.

MEDICAL/PHARMACY DIRECTORS: With this as a backdrop, the survey data in Ms Greenapple's article are very relevant, clearly showing that the cost of oncology care—driven by increasing numbers of patients, greater survival rates, and the ever-growing cost of care—is an area of major concern for all health plans and pharmacy benefit managers. It is unclear, however, how health plans will be able to effectively manage this cost trend and maintain affordability. In an era of healthcare reform that is enrolling more individuals into the insured population, this issue is certain to grow in scope.

Health plans must find new solutions to manage this trend. This will require meaningful comparative effectiveness research, guideline and pathway management that keeps up with changing technologies, and providers' commitment to consider fiscal, as well as clinical, responsibility when managing patients with cancer. Current therapies are simply too expensive to ignore cost. It is hoped that new entities, such as accountable care organizations, will bring new solutions to augment the efforts of health plans. Meanwhile, plans must continue to look for new and better ways to manage these patients. Personalized medicine, gene-expression testing, and other gene-based tests may provide help, but the role of such testing for effectively managing most cancers remains unclear. The next decade will bring many important developments in cancer; health plans must be willing to try new solutions to effectively manage this area of medical care.

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